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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ARIANI, KADE	

ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/581,678	HU ET AL.	
	Examiner	Art Unit	
	KADE ARIANI	1651	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 30 June 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because

(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ They raise the issue of new matter (see NOTE below);

(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☒ Applicant's reply has overcome the following rejection(s): Claims 11 &13 under 35 U.S.C. 112,2nd paragraph, and claims 1, 4-10, and 13-14 under 35 U.S.C. 102(b).

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: *1-47*.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: The claims remain rejected for the reasons of record.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

Dhara et al. teach an aqueous dispersion of hydrogel comprising, interpenetrating polymer network (IPN) wherein each IPN comprises a first polymer network interpenetrating a second polymer network; and an aqueous medium, the first polymer comprises poly (-N-isopropylacrylamide) and the second polymer comprises poly (acrylic acid), total polymer concentration 2 wt %, weight ratio 2:1 (p.3618 1st column 2nd an d 3rd paragraphs), the hydrogel can undergo a reversible gelation in response to a change in stimulus applied thereon, the stimulus is a change in temperature, Tg is about 34ºC (p. 3618 2nd column , 2nd and 3rd paragraphs).

Dhara et al. teach a method of preparing an IPN comprising, providing a first mono-dispersed polymer nanoparticles prepared by mixing first monomer, a first cross linking agent, and first initiator at a first temperature, adding to the first mono-dispersed polymer nanoparticles a second monomer, a second cross linking agent, a second initiator and an activator, mixing the solutions for a period of time at a second temperature, isolating the hydrogels, N, N'-methylenebisacrylamide (BIS), and potassium persulfate, poly (acrylic acid), ammonium persulfate, and TEMED, at about 21□C (ambient temperature) (p.3618, 1st column 2nd & 3rd paragraphs, and 5th paragraph).

Dhara et al. is silent about the size of the IPNs (being in nano range) and the hydrodynamic radius, core-shell configuration, and do not teach the hydrogel further comprising a drug, mixing with a surfactant, mixing the isolated IPN with a biologically active material at a third temperature. However, the method steps taught by Dhara et al. is the same or similar to the claimed process, and Dhara et al. hydrogels perform the identical function specified in the claim, undergo a reversible gelation in response to a change in stimulus applied, thus, Dhara et al. hydrogels must be similar or obvious variant of the claimed hydrogel nanoparticles and must have similar physical properties.

Moreover, Gan & Lyon teach application of hydrogel nanoparticles for drug delivery, and polymerization by mixing with SDS (surfactant). Gan & Lyon further teach the size of the particles was controlled via varying concentration of SDS during polymerization (p.7512, 2nd column line 9, and last paragraph lines 5-7).

Dhara et al. do not teach cross-linking agents EDAC and adipic acid dihydrazide. However, at the time the invention made, EDAC, a highly efficient reagent to crosslink water-soluble polymers with amide bonds, and adipic acid dihydrazide, a less toxic cross linking agent for aldehyde-mediated crosslinking of polymers), were both being used in the art as crosslinking agents for hydrogel preparation (Hennink & Nostrum, p. 19 column 1& Fig 4., p.20, column 1).

Furthermore, Dhara et al. teach the incorporation of acrylic acid network imparts anionic character to the IPNs. PNIPA is a temperature sensitive polymer whereas PAA is pH sensitive. The presence of poly (acrylic acid) (PAA) network makes the system highly swelling hydrogel. The effect of PNIPA and its shrinkage above transition temperature is only observed in compositions with high PNIPA content. As PAA content increases the IPN remains uniformly swollen at all temperatures (p.3618 2nd column 2nd paragraph).

Further motivation is in Kubota et al. who teach the application of stimuli and swelling-controlled hydrogels in drug delivery and the need for gels that can change the release rate of incorporated drugs according to the stimuli.

Therefore, a person of ordinary skill in the art would have been motivated to modify the method as taught by Dhara et al. according to the teachings of Gan & Lyon and Hennink & Nostrum to provide an aqueous dispersion of hydrogel nanoparticles and a method of preparing hydrogel nanoparticles. The motivation as taught by Kubota et al. would be to provide stimuli and swelling-controlled hydrogels that can change the release rate of incorporated drugs according to the stimuli.

Applicant's arguments with respect to the rejection claims 1- 47 under 35 U.S.C. 103(a), have been fully considered but they are not persuasive.

Applicant argues that Dhara reference does not teach IPN nanoparticles of hydrogel nanoparticles dispersed in water, but rather teaches a continuous sheet of hydrogel, and the hydrogel taught in Dhara reference is produced by a method which does not produce nanoparticles. But applicant fails to show the difference.

Applicant argues that Dhara reference describes the steps in a method forming a hydrogel with an interpenetrating network of PNIPA and PAA, and although water is used in the preparation, the final product is a hydrogel and not a dispersion of nanoparticles in an aqueous medium, and since hydrogel pieces are dried the final product is not a liquid, but rather solid.

However, hydrogels are polymeric networks which absorb and retain large amounts of water. I the polymeric network hydrophilic groups are present which are hydrated in an aqueous environment thereby creating the hydrogel structure (see Hennink et al. Introduction 1st column line 1-5). Dhara et al. teach hydrogels prepared from IPN networks of PHIPA and PAA. Therefore, Dhara et al. teach an aqueous preparation of hydrogels

Moreover, the method steps taught by Dhara et al. is the same or similar to the claimed process, and Dhara et al. hydrogels perform the identical function specified in the claim, undergo a reversible gelation in response to a change in stimulus applied, thus, Dhara et al. teach an aqueous dispersion of hydrogel.

Applicant argues that there is no suggestion or specific instruction in any of the cited references for producing an aqueous dispersion of hydrogel nanoparticles substantially lacking core-shell configuration.

However, the claims would have been obvious because a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and with a reasonable expectation of success. In addition it is not necessary to find motivation in the references themselves.